

REMARKS

Please reconsider the application in view of the above amendments and the following remarks.

Disposition of Claims

Claims 1-55 were pending in this application. Claims 3-20, 24-39, and 43-55 have been withdrawn by the Examiner. Claims 1 and 40 have been amended in this response. No new matter has been added by way of these amendments, which are supported at least in Figs. 15-17 of the application as filed.

Examiner Interview

Applicants thank the Examiner for the telephone interview conducted on January 22, 2003. During the interview, the instant claims were discussed in view of the prior art cited by the Examiner in the Office Action of October 7, 2003. Although no specificity was provided regarding the prior art basis for the rejections, the Examiner did categorize the instant claims as "overly broad." The Examiner further stated that the use of bony landmarks to delineate the metes and bounds of the instant claims was impermissible, despite Applicant's observation that the asserted prior art and Applicant's own issued patent use such language.

During the interview and a telephonic follow-up, Applicant requested that the Examiner suggest language that may be more acceptable in furtherance of the prosecution of this application. The Examiner was unable to provide any such language, although she did state that, after consulting with her supervisor and peers in her subject area, there was

agreement that the instant claims were "overly broad."

A In light of this lack of guidance or disclosure with respect to any specific disclosure in the prior art that would be applicable to the asserted rejections, Applicants have further limited the claim scope in a good faith effort to address the Examiner's concerns.

Rejections under 35 U.S.C § 103

Claims 1-2 and 40-42 stand rejected under 35 U.S.C. § 103 as obvious over U.S. Patent No. 6,092,314, issued to Rothbart ("Rothbart"). Claims 1 and 40 have been amended in this reply to clarify the present invention recited. To the extent that this rejection may still apply to the amended claims, the rejection is respectfully traversed.

Amended claim 1 recites an orthopedic appliance comprising a wedge for placement beneath a toe and *forward of the center of a first metatarsal* (shown as 36 in the following Figure), and having a first upper surface disposed between an apex and a first end, and a second upper surface disposed between an apex and a second end, wherein the first upper surface is disposed at an angle of inclination relative to the lower planar surface in a direction substantially parallel to the medial column of the foot, whereby *a distal end of a proximal phalanx (46) is raised with respect to a distal end of the first metatarsal (36)*. In contrast to such a device, Rothbart discloses a forefoot support surface having a back edge positioned **posterior to the first metatarsal (36) but anterior to a plantar surface of the calcaneus (27)** (Col. 6, ll. 30-32).

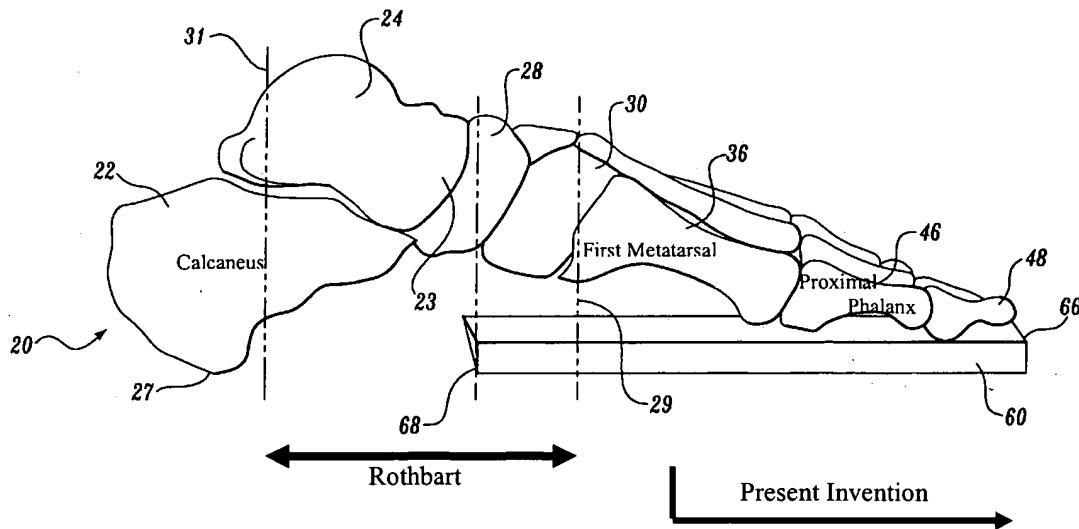
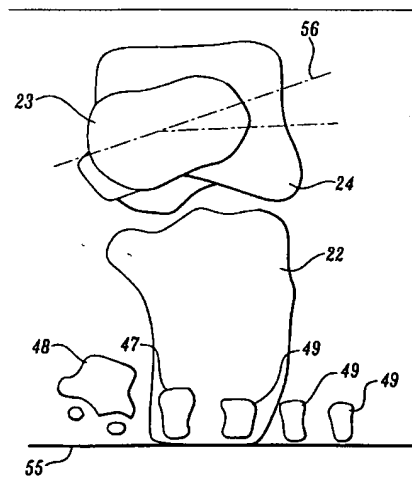


FIGURE 6
(ROTHBART)

As shown in Figure 6, and described at Col. 6, ll. 33-37, “the back edge 68 may line in, along or between a reference line 29 at the posterior end of the first metatarsal 36 to a reference line 31 at the anterior end of the plantar surface 27 of the calcaneus 22.” Thus Rothbart is *clearly disclaiming* the location of a wedge according to claim 1 of the instant application. Furthermore, the forefoot support device according to Rothbart is configured to cause an angle of inclination across the medial column of the foot (i.e., in the transverse plane), and not in a direction that is parallel to the medial column of the foot (i.e., in the sagittal plane), as required by the instant invention. Figure 4 of Rothbart (at right) demonstrates “Rothbart’s Foot Structure.” wherein the hallux (first metatarsal) 48 is elevated and twisted. Rothbart’s invention is “directed to a foot support system that effectively builds the ground up to the medial column of a foot exhibiting Rothbart’s Foot



Structure, thereby supporting the foot in its anatomical position so that the foot does not inwardly collapse...” (Col. 6, ll. 8-12).

In contrast to Rothbart, the invention of claim 1 raises a distal end of a proximal phalanx with respect to a distal end of a first metatarsal, thereby advantageously facilitating plantarflexion of the first metatarsal through the late midstance and propulsive phases of gait (Paragraph 66 of the current application). The invention according to Rothbart instead elevates the first metatarsal and does not facilitate the biomechanical action (described above) that is an advantage of the instant invention. Therefore, withdrawal of this rejection with respect to claim 1, as well as claim 2 which depends from claim 1, is respectfully requested.

Claim 40, as amended, recites a method for improving stability of the foot comprising providing a wedge *forward of the center of a first metatarsal*, said wedge having a first and second upper surface, and *elevating a proximal phalanx relative to a first metatarsal*. In contrast, Rothbart discloses a forefoot support system **extending from the hallux to proximal to (past) the first metatarsal head** (Col. 6, ll. 24-25, 33-37 and Fig. 6). Furthermore, the forefoot support system according to Rothbart elevates the medial column of the forefoot relative to the remainder of the forefoot (i.e. the angle of inclination according to Rothbart is across the foot, i.e., in the transverse plane) as indicated by the fact that the Rothbart device “does not significantly elevate the phalanges 47 of the second toe” (Col. 6, ll. 41-42) while supporting the medial column of the forefoot in an elevated position relative to the remainder of the forefoot (Col. 6, ll. 57-58). Thus, Rothbart supports the entire medial column relative to the rest of the forefoot (i.e. inclination is across the foot – see Figure 6 above), in contrast to the support method

of claim 40 that elevates a proximal phalanx relative to a first metatarsal (i.e. inclination is parallel to the foot).

Furthermore, Applicant fails to discern the Examiner's basis for the statement that the Rothbart device "elevates a proximal phalanx to a predetermined angle of inclination using the wedge, relative to a first metatarsal" (Office Action at p. 3). Neither the specification nor the figures of Rothbart suggest any such functionality. In view of these distinctions claim 40, and claims 41-42 which depend from claim 40, are patently distinct over Rothbart. Accordingly, withdrawal of this rejection is respectfully requested.

Claims 21-23 stand rejected under 35 U.S.C. § 103 as obvious over Rothbart. This rejection is respectfully traversed.

Claim 21 recites an apparatus for orthopedic treatment comprising a support which maintains the proximal phalanx at an angle of inclination *relative to a first metatarsal*. As previously discussed with regard to claim 40, above, Rothbart discloses a forefoot support system extending from the hallux to proximal to (past) the first metatarsal head (See Col. 6, ll. 24-25, 33-37 and Fig. 6). Accordingly, the forefoot support system elevates the medial column of the forefoot relative to the remainder of the forefoot. Thus, the biomechanical basis of the Rothbart device is contrary to that of the current invention, which advantageously allows for retrograde plantarflexion of the first metatarsal head.

Applicant fails to discern the Examiner's basis for the statement that the Rothbart device "maintains the proximal phalanx at an angle of inclination... relative to a first metatarsal" (Office Action at p. 3). Although the Examiner references Col. 6, ll. 66-67,

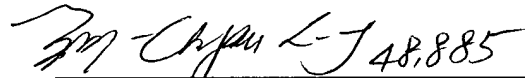
Col. 7, ll. 1-19, and Fig. 10, none of these contain a relevant disclosure. Col. 6, ll. 66-67 discusses a **downward slope** of the upper surface of the foot support system. Col. 7, ll. 1-19 discuss various configurations of the foot support system, none of which relate to an **inclination** of a proximal phalanx relative to a first metatarsal. Finally, Fig. 10 is a **cross-section** of the foot support system (see Col. 3, ll. 5-8) and therefore cannot possibly disclose an angle of inclination **along the medial column of the foot**. In fact, there is no suggestion in the specification or figures of Rothbart of a device which maintains the proximal phalanx at an angle of *inclination relative to a first metatarsal*. Instead, Rothbart supports the entire medial column relative to the rest of the forefoot. For at least these reasons, claim 21 is patentable over Rothbart. Claims 22-23, which depend from claim 21, are similarly patentable. Accordingly, withdrawal of this rejection is respectfully requested.

Conclusion

Applicants believe this reply is fully responsive to all outstanding issues and places this application in condition for allowance. If this belief is incorrect, or other issues arise, the Examiner is encouraged to contact the undersigned or his associates at the telephone number listed below. Please apply any charges not covered, or any credits, to Deposit Account 50-0591 (Reference Number 09166.002002).

Respectfully submitted,

Date: 3/8/04

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